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Washington, D.C. 20231

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In Re: Patent Term Extension
Application for
U.S. Patent No. 5,164,194

#30

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,164,194, which claims the method of use of the human drug product ASTELIN®, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 349 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 349 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of April 4, 1997 (62 Fed. Reg. 16,167). Under 35 U.S.C. § 156(c):

Period of Extension = ½ (Testing Phase) + Approval Phase
= (0) + 2,048 - 602
= 1,446 days

Since the regulatory review period began March 8, 1989, before the patent issued, November 17, 1992, only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period. 35 U.S.C. § 156(c). The testing phase of an approved product is defined as the period beginning on the date that an exemption under subsection 505(i) of the Federal Food Drug and Cosmetic Act became effective for the approved product, March 8, 1989, and ending on the date an application for the approved product was initially submitted under subsection 505(b), March 26, 1991. Since both of these dates were before the issue date of the patent, none of the testing phase has been considered. The approval phase of a product begins on the date the application for the approved product was initially submitted. For ASTELIN®, this date was March 26, 1991, which was before the issue date of the patent, November 17, 1992. Accordingly, since from March 26, 1991 to November 17, 1992 is 602 days; this period is subtracted from the number of days occurring in the approval phase according to the FDA determination of the length of the regulatory review period. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product (November 1, 1996) plus any patent term extension cannot exceed fourteen years. The period of extension calculated above 1,446 days, would extend the patent to November 2, 2013, which is beyond the 14 year limit (14 years after the approval date is November 1, 2010) set forth in 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its expiration date, November 17, 2009, to and including November 1, 2010, or 349 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	:	5,164,194
Granted	:	November 17, 1992
Original Expiration Date	:	November 17, 2009
Applicant	:	Helmut Hettche
Owner of Record	:	Asta Medica, AG
Title	:	Azelastine Containing Medicaments
Classification	:	424/489
Product Trade Name	:	ASTELIN® (azelastine hydrochloride)
Term Extended	:	349 days
Expiration Date of Extension	:	November 1, 2010

Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

By hand: One Crystal Park, Suite 520
2011 Crystal Drive
Arlington, VA

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin L. Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
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Rockville, MD 20857

RE: ASTELIN®
FDA Docket No.: 97E-0014